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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,799	11/23/2001	George Jackowski	2132.086	5599
21917	7590	05/24/2006	EXAMINER	
MCHALE & SLAVIN, P.A. 2855 PGA BLVD PALM BEACH GARDENS, FL 33410			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,799

Applicant(s)

JACKOWSKI ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) 39-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2005 has been entered.

Formal matters

2. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

3. Claim 1 has been amended as requested in the amendment of Paper filed on June 27, 2005. Claims 1 and 39-46 are pending in the instant application.

Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to an invention nonelected by original presentation, there being no allowable generic or linking claim (see Paper mailed on November 25, 2003).

Claim 1 is under examination in the instant office action.

4. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1649

5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

6. Applicant's arguments filed on June 27, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility essentially for reasons of record with respect to the 35 U.S.C. 112, first paragraph, lack of enablement rejection in previous office actions of record. Applicant's traversal of the 35 U.S.C. 112, first paragraph rejection as submitted on June 27, 2005 is answered below.

Claim 1, as currently amended, is directed to a biopolymer marker consisting of amino acid sequence 2-18 of SEQ ID NO: 1. It is noted at page 20 of the Response that Applicant refers to supposed amendment of the claim to indicate that "the isolated peptide consisting of amino acid residues 2-18 of SEQ ID NO: 1 is linked to Alzheimer's disease". However, there appears to be no such amendment of record presented within the text of claim 1.

Further, it is important to point out that throughout the text of the Response filed on June 27, 2005, Applicant submits that the instant claimed peptide 2-18 of SEQ ID NO: 1 is not diagnostic for Alzheimer's Disease (AD) or any other pathological condition but is linked to AD

Art Unit: 1649

(middle at p. 21, pp.28-29, especially top at p. 30). The instant specification presents several definitions of a “biopolymer marker” (see pages 5, 6 especially 11 and 21), essentially that it is a polymer of biological origin (bottom at page 21), which can be present/absent/down-regulated/upregulated with respect to a disease condition (page11). However, according to Webster dictionary “a marker” is “one that marks or distinguishes”. The instant invention is based on the assertion that a peptide fragment 2-18 of SEQ ID NO: 1 is differentially expressed in patients suspected of having AD from control normal individuals. There appears to be no further information presented in the instant specification as to what constitutes finding of a peptide 2-18 of SEQ ID NO: 1 in a sample. For example, if a peptide 2-18 of SEQ ID NO: 1 was found in a sample obtained from a patient, what would that mean to the skilled practitioner? Does it mean that a patient has AD, or is at risk of developing the disease? The instant specification fails to provide any factual evidence that finding of a peptide 2-18 of SEQ ID NO: 1 could lead to any meaningful determination for diagnosis or treatment of Alzheimer’s diseases, as asserted by Applicant. Thus, in order to practice the claimed invention, a skilled artisan would have to engage in a substantial amount of further research to establish what constitutes “link to Alzheimer’s disease” and, eventually, establish the utility of the claimed peptide 2-18 of SEQ ID NO: 1 in the diagnostics of Alzheimer’s.

At pp. 21-28 of the Response, Applicant traverses the instant rejection on the premises that the specific and substantial credible utility of the claimed biopolymer marker as being linked Alzheimer’s disease (AD) is based on the showing “that the biopolymer marker (amino acid residues 2-18 of SEQ ID NO: 1) is present in samples of body fluid obtained from Alzheimer’s patients, but is not present in samples of body fluid obtained from patients who were age

Art Unit: 1649

matched with the Alzheimer's patients (controls)" (pp.21-22). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

The instant specification provides a disclosure of a protocol, under which samples of blood collected from AD patients, age-matched controls and pooled control samples were analyzed by using mass spectrometric and chromatographic techniques. The results of the analysis are presented in Figure 1 and also within the text of the instant specification. Specifically, finding of the "disease specific marker" identified by an amino acid sequence is presented at page 46 of the instant specification. Figure 1 is described as "photograph of a gel which is indicative of the presence/absence of the marker in disease vs. control and, in cases where the marker is always present, the relative strength, e.g. the up or down regulation of the marker relative to categorization of diseases state is deduced" (p. 46). Brief description of the Figure (page 37) does not contain any disclosure of how fragment 2-18 of SEQ ID NO: 1 corresponds to the bands as shown in Figure 1. The text on pp.45-46 is limited to the description of finding of three peptides (2-18 of SEQ ID NO: 1 among them) "related to Alzheimer's disease" and reference to Band 2. Without any further information being present in the instant specification, as filed, which includes analysis of Figure 1 and Band 2 being present only in one AD sample, it is not clear how a skilled practitioner can use the instant disclosure and peptide 2-18 of SEQ ID NO: 1 for diagnostic or clinical purposes, as currently asserted. The Examiner maintains that based on the information presented in the instant specification as originally filed, the instant claimed invention, an isolated biomarker 2-18 of SEQ ID NO: 1, asserted to be useful for diagnostics and therapeutics of Alzheimer's disease, clearly lacks specific and substantial

Art Unit: 1649

credible real-world utility and, therefore, the instant invention does not meet the requirements of 35 U.S.C. 101.

At pp.23-32 of the Response, Applicant refers to several publications to explain as how differentially expressed proteins are used as disease markers. The Examiner fully agrees that identification and selection of reliable biomarkers to diagnose pathological conditions is a known practice. Moreover, identification of a marker that is specifically associated with a particular condition (present/absent or present at specific altered levels as compared to normal control) constitutes a specific and substantial credible utility even if a biological role of the molecule itself is not known or disclosed. However, this is not a factual situation here. In the instant case, Applicant's invention is predicated on the finding that samples of blood taken from patients suspected of having AD contain proteins in the forms and amounts that are different from normal control samples. Applicant further extrapolates this result into a diagnostic tool for AD. Accordingly, it would appear that Applicant provides a single finding (the finding), and then presents an invitation to experiment to determine the level of differential expression of peptide 2-18 of SEQ ID NO: 1 that is diagnostic of AD, and then to assay if the peptide could be used to diagnose AD, such as to distinguish AD from normal state and from other similar neurodegenerative conditions, as well as to treat AD.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. *See In re Fisher*, 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility" 2005 WL 2139421, at *4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* at *5. The court held that disclosing

Art Unit: 1649

a substantial utility means “show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.” *Id.*

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because “[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage,” (*Id.*, slip op. at 15), in the instant case, detection of peptide 2-18 of SEQ ID NO: 1 in a sample of a patient suspected of having AD provides no meaningful information as to the diagnosis determination. While an assay that detects the presence of a marker that has a stated correlation to a specific disease condition would be considered a “substantial utility” in the context of providing a diagnostic tool, in the instant case the claimed peptide is suitable only for further research, which constitutes a utility that is not considered a “substantial utility”. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are “useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed “real world” utility.

Finally, with respect to Applicant’s statement that the claimed biopolymer marker is not “a unique marker for any particular disease or condition” evidences a link to Alzheimer’s disease (top at page 30), the Examiner maintains that disclosure of a peptide fragment 2-18 of SEQ ID NO: 1 as being linked to a pathological condition constitutes a utility, which requires further research to identify or reasonably confirm a “real world” context of use. At present, it appears

Art Unit: 1649

that the only information obtained from identifying the presence of a biopolymer marker 2-18 of SEQ ID NO: 1 is the determination of “a link to AD”. One skilled in the art readily appreciates that many factors have a link to or are associated with a particular pathological condition. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court specifically stated that “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion”. To grant Applicant a patent encompassing isolated fragments of a naturally occurring human protein, which are not readily usable in their current form, would be to grant Applicant a monopoly “the metes and bounds” of which “are not capable of precise delineation”. That monopoly “may engross a vast, unknown, and perhaps unknowable area” and “confer power to block off whole areas of scientific development, without compensating benefit to the public” *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed peptides based solely upon an assertion that the protein is linked to Alzheimer’s disease is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted.

Thus, since the instant specification does not disclose a credible “real world” use for the isolated biopolymer markers 2-18 of SEQ ID NO: 1 in currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

7. Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility

Art Unit: 1649

for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

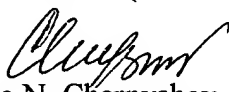
Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

May 19, 2006